

*Application No. 10/657472*  
*Page 2*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

**Amendments To The Claims:**

**Claim 1. (Previously Presented)** A catheter assembly comprising:

a catheter, the catheter comprising a catheter shaft, the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough;

a rotatable sheath, the rotatable sheath being disposed about at least a portion of the catheter shaft and rotatable about the at least a portion of the catheter shaft, the rotatable sheath having a length substantially less than that of the catheter shaft; and

a secondary guide wire housing, the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough, at least a first distal portion of the guide wire housing being engaged to at least a first proximal portion of the rotatable sheath.

**Claim 2. (Previously Presented)** A catheter assembly comprising:

a catheter, the catheter comprising a catheter shaft, the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough;

a rotatable sheath, the rotatable sheath being disposed about at least a portion of the catheter shaft and rotatable about the catheter shaft, the rotatable sheath having a length substantially less than that of the catheter shaft;

a secondary guide wire housing, the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough, at least a first distal portion of the guide wire housing being engaged to at least a first proximal portion of the rotatable sheath; and

a stent, the stent being expandable from a reduced stent state to an expanded stent state, and defining a flow path between a proximal end opening and a distal end opening, the stent being at least partially constructed from a plurality of interconnected stent members that define a plurality of cell openings therebetween, each of the cell openings being in fluid communication with the flow path, in the reduced stent state the stent is disposed about at least a portion of the rotatable sheath and at least a portion of the secondary guide wire housing, a distal end portion of the secondary guide wire housing exiting the flow path of the stent through one of the plurality of cell openings.

*Application No. 10/657472*  
*Page 3*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

Claim 3. (Original) The assembly of claim 2 wherein the stent is selected from at least one member of the group consisting of: a self-expanding stent, a balloon-expandable stent, a hybrid expandable stent and any combination thereof.

Claim 4. (Original) The assembly of claim 1 wherein the catheter shaft further comprises a medical balloon fixedly mounted thereto, the medical balloon expandable from a reduced configuration to an expanded configuration, the catheter shaft further defining an inflation lumen, the inflation lumen being in fluid communication with the medical balloon.

Claim 5. (Original) The assembly of claim 4, wherein the rotatable sheath is rotatably disposed about at least a portion of the medical balloon.

Claim 6. (Original) The assembly of claim 2 wherein at least a portion of the stent is coated with at least one therapeutic agent.

Claim 7. (Original) The assembly of claim 6 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-mitotic agents such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating

*Application No. 10/657472*  
*Page 4*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

Claim 8. (Original) The assembly of claim 6 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor  $\alpha$  and  $\beta$ , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor  $\alpha$ , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the DNA's encoding them and any combinations thereof.

Claim 9. (Original) The assembly of claim 6 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.

Claim 10. (Original) The assembly of claim 9 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34<sup>-</sup> cells; lineage negative CD34<sup>+</sup> cells; lineage negative cKit<sup>+</sup> cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells;

*Application No. 10/657472*  
*Page 5*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

immunologically masked cells; tissue engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.

Claim 11. (Original) The assembly of claim 6 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes including polypropylene, polyethylene and high molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL<sup>®</sup>, etc.), fibrin, collagen and derivatives thereof; polysaccharides such as celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO<sub>4</sub>'s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.

*Application No. 10/657472*  
*Page 6*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

Claim 12. (Original) The assembly of claim 5 further comprising a lubricious coating, the lubricious coating positioned between at least a portion of the rotatable sheath and at least a portion of the medical balloon.

Claim 13. (Previously Presented) A catheter assembly comprising:

a catheter, the catheter comprising a catheter shaft, the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough;

a rotatable sheath, the rotatable sheath being disposed about at least a portion of the catheter shaft and rotatable about the catheter shaft, the rotatable sheath having a length substantially less than that of the catheter shaft and being rotatably disposed about at least a portion of the medical balloon;

a secondary guide wire housing, the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough, at least a first distal portion of the guide wire housing being engaged to at least a first proximal portion of the rotatable sheath;

a medical balloon fixedly mounted to the catheter shaft, the medical balloon expandable from a reduced configuration to an expanded configuration, the catheter shaft further defining an inflation lumen, the inflation lumen being in fluid communication with the medical balloon; and

a rotatable collar, the rotatable collar rotatably disposed about a portion of the catheter shaft proximal of the medical balloon, at least a first proximal portion of the secondary guide wire housing being engaged to at least a portion of the rotatable collar.

Claim 14. (Original) The assembly of claim 13 wherein the rotatable collar defines a catheter shaft lumen therethrough, the catheter shaft being positioned within the catheter shaft lumen, the catheter shaft lumen having a diameter greater than an outer diameter of the catheter shaft.

Claims 15-18. (Canceled)

Claim 19. (Original) The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a hydrophilic polymer material.

Claim 20. (Original) The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a hydrophilic material.

*Application No. 10/657472*  
*Page 7*

*Amendment*  
*Attorney Docket No. S63.2H-11273-US01*

Claim 21. (Original) The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a first material and a second material.

Claim 22. (Original) The assembly of claim 21 wherein the rotatable sheath is at least partially constructed from at least one material of the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene, polyamide, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

Claim 23. (Original) The assembly of claim 21 wherein the first material is a polymer matrix and the second material is at least one distinct member of reinforcing material at least partially supported within the polymer matrix.

Claim 24. (Original) The assembly of claim 23 wherein polymer matrix is selected from at least one material from the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene and any combination thereof.

Claim 25. (Original) The assembly of claim 23 wherein the reinforcing material is selected from at least one material of the group consisting of polyamide, polyethylene, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

Claims 26-35. (Canceled)